REMARKS

I. Claim Cancellations

Claims 1-27 were pending in the present application. In order to further Applicants' business interests, and not in acquiescence to the arguments of the Office Action, claims 11-13, 15, 16, and 18-27 have been cancelled. Applicants reserve the right to pursue the cancelled claims in one or more continuing applications.

II. New Claims

New claims 28-44 have been added.

Support for new claims 28 and 29 can be found for example, throughout the specification and in Tables 1 and 6.

Support for new claim 30, wherein the bioagent is identified at the sub-species level, is found, for example, on page 23, lines 11-19.

New claim 31, recites the selection of at least one pair of oligonucleotide primers, wherein one member of the pair of primers hybridizes to a first conserved region of nucleic acid encoding a protein involved in translation, replication, recombination and repair, transcription, nucleotide metabolism, amino acid metabolism, lipid metabolism, uptake or secretion and the other member of the pair of primers hybridizes to a second conserved region of nucleic acid encoding a protein involved in translation, replication, recombination and repair, transcription, nucleotide metabolism, amino acid metabolism, lipid metabolism, uptake, secretion, antibiotic resistance, virulence, or pathogenicity wherein the first and second conserved regions flank a variable nucleic acid region which varies among bioagents. Support for these claim elements can be found, for example, on page 11, lines 5-8 as well as page 23, lines 14-16. Claim 31 further recites the steps of amplifying nucleic acid from the bioagent with the pair of oligonucleotide primers to produce an amplification product, determining the molecular mass of the amplification product by mass spectrometry, calculating the base composition of the amplification product from the molecular mass; and comparing the base composition to calculated or measured base compositions of amplification products of known bioagents produced by using the pair of oligonucleotide primers, thereby identifying the bioagent. Support for these amendments can be found, for example in Example 3 on pages 27-30.

Support for new claims 32-41 is found, for example, in original claims 2-10, 14 and 17 and on pages 23-25 which describe environmental testing methods.

Support for new claims 42 and 43 can be found for example, throughout the

specification and in Tables 1 and 6, for example.

Support for new claim 44, wherein the bioagent is identified at the sub-species level, is found, for example, on page 23, lines 11-19.

All of the added claims are fully supported in the specification and do not comprise new matter.

Upon entry of the amendment, claims 1, 2, 4-10, 14, 17, and 28-44 will be pending.

II. Claim Amendments

Claims 1 and 17 are currently amended.

Claim 1 has been amended to recite the selection of least one pair of oligonucleotide primers, wherein one member of the pair of primers hybridizes to a first conserved region of nucleic acid encoding ribosomal RNA and the other member of said pair of primers hybridizes to a second conserved region of nucleic acid encoding ribosomal RNA wherein said first and second conserved regions flank a variable nucleic acid region which varies among bioagents. Support for this amendment can be found, for example, on page 13, lines 24-34 and also in Figures 1 and 2 which indicate that the primers hybridize to conserved regions of nucleic acid encoding ribosomal RNA.

Claim 1 has been further amended to recite the steps of amplifying nucleic acid from the bioagent with the pair of oligonucleotide primers to produce an amplification product, determining the molecular mass of the amplification product by mass spectrometry, calculating the base composition of the amplification product from the molecular mass; and comparing the base composition to calculated or measured base compositions of amplification products of known bioagents produced by using the pair of oligonucleotide primers, thereby identifying the bioagent. Support for these amendments can be found, for example in Example 3 on pages 27-30.

Claim 17 has been amended to delete the word "virus."

III. Priority

The Office Action indicates that claims 3, 18 and 19 lack support in the parent application Serial No. 09/798,007. Applicants wish to point out that claims 18 and 19 have been cancelled in the current amendment. With respect to claim 3, Applicants assert that support for "air samples" is implicit in the description of the parent application. Paragraph [0034] of US20030027135 (09/798,007) indicates that the method is useful in a wide variety of fields including environmental and germ warfare testing which would include the testing of air samples.

III. Claim Interpretation

The Office Action interprets the meaning of the phrase "wherein both first and second bioagent identifying amplicons are correlative" to mean that the "correlative amplicons" are amplified by the same primers. In order to further Applicants' business interests, and not in acquiescence to the arguments of the Office Action, the Applicants have amended claim 1 and provided new claim 31 to read: "...comparing said base composition to calculated or measured base compositions of amplification products of known bioagents produced by using said pair of oligonucleotide primers"

The Office Action interprets the meaning of the term "molecular mass" broadly to encompass any mode of determination of molecular mass. In order to further Applicants' business interests, and not in acquiescence to the arguments of the Office Action, the Applicants have amended claim 1 and provided new claim 31 to read "determining the molecular mass of said amplification product by mass spectrometry."

IV. Response to Claim Rejections

Novelty

A. Claims 1, 2, 4-7, 11, 17, 20, 21 and 27 have been rejected under 35 U.S.C. 102(b) as being anticipated by Hurst, 1998.

B. Claims 1, 6, 7, 14-17, 20, 21 and 24-27 have been rejected under 35 U.S.C. 102(b) as being anticipated by Muddiman, 1996.

C. Claims 1, 2, 4-9, 11, 17, 20, 21, and 27 have been rejected under 35 U.S.C. 102(b) as being anticipated by Lupski 5,523,217 (the '217 patent).

Obviousness

D. Claim 3 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Hurst, 1998, in view of Kohne 5,567,587 (the '587 patent).

E. Claims 9, 10 and 18 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Hurst, 1998 in view of Romick 6,468,743 (the '743 patent).

F. Claims 12, 13, 22 and 23 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Muddiman, 1996, in view of Koster WO 98/20166 (the '166 patent).

G. Claim 19 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Hurst, 1998, in view of the '743 patent and further in view of Haugland, 1998.

Obviousness-Type Double Patenting

H. Claims 1-27 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 59, 60, 62, 63, 66, 69-76 and 79-94 of co-pending Application Serial No. 10/156,608.

I. Claims 1-27 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of co-pending Application Serial No. 10/660,997 in view of Muddiman.

V. The Claimed Invention is Novel

A claim is anticipated only if each and every element as set forth in the claim is found either expressly or inherently described in a single prior art reference. MPEP 2131, citing *Verdegaal Bros v. Union Oil Co. of California, 814, F.2d. 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)*. As explained in more detail below, Hurst, 1998, Muddiman, 1996 and the '217 patent do not set forth each and every element of currently pending claims 1, 2, 4-10, 14, 17, and 28-44.

A. The Claimed Invention is not Anticipated by Hurst, 1998.

Claims 1, 2, 4-7, 11, 17, 20, 21 and 27 have been rejected under 35 U.S.C. 102(b) as being anticipated by Hurst, 1998. Claims 11, 20, 21 and 27 have been cancelled thereby rendering rejection of these claims moot. Applicants assert that in light of the current amendment of claim 1, this claim and all pending claims dependent thereon, are not anticipated by Hurst, 1998. Hurst does not disclose amplification using primers that hybridize to nucleic acid encoding ribosomal RNA. To the contrary, Hurst teaches a process of specific amplification of nucleic acid of two types of methanotrophic bacteria using primers that hybridize to the *pmoA* gene (see Abstract).

Further, Applicants assert that new claims 31 and all pending claims dependent thereon are not anticipated by Hurst, 1998. Hurst does not teach amplification using primers that hybridize to nucleic acid encoding a protein that participates in translation, replication, recombination and repair, transcription, nucleotide metabolism, amino acid metabolism, lipid metabolism, uptake, secretion, antibiotic resistance, virulence, or pathogenicity as recited by claim 31. To the contrary, the target *pmoA* gene taught by Hurst encodes a methane monooxygenase gene that encodes an enzyme responsible for mono-oxygenation of methane.

In addition, Hurst does not describe calculation and comparison of base compositions of amplification products as recited in amended claim 1 and new claim 31.

For the reasons argued above, Applicants submit that amended claim 1, new claim 31 and all currently pending claims dependent thereon, are not anticipated by Hurst, 1998.

B. The Claimed Invention is Not Anticipated by Muddiman, 1996.

Claims 1, 6, 7, 14-17, 20, 21 and 24-27 have been rejected under 35 U.S.C. 102(b) as being anticipated by Muddiman, 1996. Claims 15-16, 20, 21, 24-27 have been cancelled, thus rendering these rejections moot. In light of the current amendment of claim 1, this claim, as well as new claim 31 and all pending claims dependent thereon, are not anticipated by Muddiman, 1996. These current claims recite a step of calculating base composition of the amplification product from its molecular mass. Muddiman, 1996 does not anticipate these claims because, as conceded by the Examiner in the Office Action of February 28, 2006 on page 10 (last sentence), "Muddiman does not teach base compositions." Nor does Muddiman teach hybridization of primers to nucleic acid encoding proteins that participate in translation, replication, recombination and repair, transcription, nucleotide metabolism, amino acid metabolism, lipid metabolism, uptake, secretion, antibiotic resistance, virulence, or pathogenicity as recited by claim 31.

For the reasons argued above, the Applicants submit that the currently pending claims are not anticipated by Muddiman, 1996.

C. The Claimed Invention is Not Anticipated by Lupski U.S. Patent 5,523,217

Claims 1, 2, 4-9, 11, 17, 20, 21, and 27 have been rejected under 35 U.S.C. 102(b) as being anticipated by Lupski 5,523,217 (the '217 patent). Claims 11, 20, 21 and 27 have been cancelled, thus rendering these rejections moot. The Applicants assert that the claims as amended, as well as the newly presented claim 31 and new claims dependent thereon, are not anticipated by the '217 patent, because the '217 reference does not teach calculation and comparison of base compositions of amplification products.

VI. The Claimed Invention is Not Obvious

Prima facie obviousness requires 1) a suggestion or motivation in the references to

combine or modify the reference teachings; 2) the prior art must provide reasonable expectation of success should the suggested combination or modification take place; and 3) the prior art must teach or suggest all of the claim limitations. A showing of obviousness will fail if any of these elements is not met.

D. Hurst, 1998 in View of Kohne

Claim 3 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Hurst, 1998, in view of the '587 patent. Applicants assert that the combination of Hurst and the '587 patent do not teach or suggest each of the claim limitations because, for example, the teaching of calculation of base compositions is absent in both references.

E. Hurst, 1998 in view of Romick

Claims 9, 10 and 18 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Hurst, 1998 in view of the '743 patent. Applicants note that claim 18 has been cancelled and submit that the combination of Hurst 1998 and Romick do not teach or suggest all of the elements of claims 9 and 10 because, for example, the teaching of calculation and comparison of base compositions is absent in both references.

Furthermore, there is no motivation to combine the teachings of the primary reference (Hurst, 1998) with the teachings of the '743 patent to arrive at the claimed invention. Hurst 1998 discloses a method for "characterization of the ability of microbial populations to destroy pollutants in groundwater and soil at contaminated industrial sites" (See Abstract). The Hurst reference makes no suggestion of a combination with the '743 patent and does not provide a teaching of a reasonable expectation of success of a combination of its method with analysis of products including cosmetics or foodstuffs.

F. Muddiman, 1996 in view of Koster '166

Claims 12, 13, 22 and 23 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Muddiman, 1996, in view of Koster WO 98/20166 (the '166 patent)" Applicants have cancelled these claims which obviates the specific rejections of claims 12, 13, 22 and 23.

G. Hurst, 1998 in view of Romick '743 and Further in View of Haugland,

1998

Claim 19 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Hurst, 1998, in view of the '743 patent and further in view of Haugland, 1998. Applicants wish to point out that claim 19 has been cancelled which should obviate this rejection. In addition, combination of Hurst 1998 with Romick and further with Haugland do not teach or suggest all of the elements of the claim because the teaching of calculation and comparison of base compositions is lacking in each of the three references. Furthermore, there is no motivation to combine the teachings of the primary reference (Hurst, 1998) with the teachings of the '743 patent and further with Haugland to the to arrive at the claimed invention because Hurst 1998 is concerned with a method for "characterization of the ability of microbial populations to destroy pollutants in groundwater and soil at contaminated industrial sites" (See Abstract). The Hurst reference makes no suggestion of a combination with the '743 patent or with Haugland and does not provide a teaching of a reasonable expectation of success of a combination of its method with analysis of molds.

III. Obviousness-Type Double-Patenting

As requested in the Office Action dated 02/18/2006, point 15, while making no admission with regard to obviousness-type double patenting, Applicant herein identifies all of the co-pending applications of the same patent family which the Examiner may wish to review with regard to obviousness-type double patenting: 10/156,608, 10/660,997, 10/660,122, 10/660,998, 11/233,630, 11/331,978, and 11/331,987.

H. Co-pending Application Serial No. 10/156,608

Claims 1-27 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 59, 60, 62, 63, 66, 69-76 and 79-94 of co-pending Application Serial No. 10/156,608. A terminal disclaimer with regard to 10/156,608 is filed herewith.

I. Co-pending Application Serial No. 10/660,997 in view of Muddiman, 1996

Claims 1-27 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of co-pending Application Serial No. 10/660,997 in view of Muddiman, 1996. A terminal disclaimer with regard to 10/660,997 is filed herewith.

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Conclusions

In view of the foregoing, Applicants submit that the claims of the instant application are in condition for allowance. The Examiner is invited to contact Applicants' undersigned representative if there should be any questions with regard to the claimed invention.

Respectfully submitted,

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